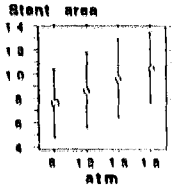
stent areas continue to increase at pressures above 16 atm. To determine whether these responses are stent-design specific, we studied 28 lesions treated with single AVE Micro II stents. Sequential intravascular ultrasound (IVUS) was performed after adjunt PTCA at 8, 12, 15, and 18 atm. IVUS measurements included *reference* (ref) lumen and minimum stent areas (mm^2), stent expansion (stent/reference lumen area), and stent symmetry (minimum/maximum stent diameter).

	8 atm	12 atm	15 atm	18 atm	p
Ref lumen area	10.7 ± 3.3	10.9 ± 3.6	11.9 ± 4.0	12.3 ± 4.4	0.0017
Sent area	7.7 ± 2.6	8.6 ± 3.0	9.6 ± 3.2	10.7 ± 2.9	<0.0001
Expansion	71 ± 14	80 ± 20	84 ± 17	90 ± 18	<0.0001
Eccentricity	82 ± 10	80 ± 9	82 ± 9	83 ± 11	0.7400

Minimum stent area increased linearly from 8 to 18 atm ($p < 0.0001$ for all comparisons, Figure). Because reference lumen area also increased progressively, the impact of high pressure PTCA on expansion was not as dramatic as on minimum stent area: 8 to 12 atm ($p = 0.0047$), 12 to 15 atm ($p = 0.0132$), and 15 to 18 atm ($p = 0.0449$). Stent symmetry was not affected by high pressure PTCA.



We conclude: High pressure adjunct PTCA progressively increased minimum stent areas within AVE stents without a plateau at pressures < 18 atm. These responses to high pressure PTCA are similar to those reported for tubular slotted stents and, therefore, appear to be stent design *non*specific.

1215-105 Acute and Preliminary Follow-up Results of the "OPTimization With ICUS to Reduce Stent Restenosis" (OPTICUS) Trial

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The "OPTimization with ICUS to reduce stent restenosis" (OPTICUS) trial is a multicenter, randomized trial in 550 patients to test the hypothesis that intracoronary ultrasound (ICUS) guidance during stent implantation reduces the restenosis rate (primary endpoints: <50% angiographic diameter stenosis and angiographic MLD at 6 months, secondary endpoints: 12 months clinical follow-up, economic assessment). ICUS-guidance to optimize stent expansion is performed according to MUSIC-study criteria. Relevant inclusion criteria represent: de novo or restenosic lesions, lesions length < 25 mm, reference segment diameter ≥2.5 mm, < 2 stents per lesion. To date 289 patients have been randomized, we expect to have completed inclusion of patients at the beginning of 1998 and we will be able to present acute clinical and procedural data.

In 169 lesions analyzed angiographically the mean reference diameter is 2.98 ± 0.53 mm with 32 lesions (19%) <2.5 mm, average lesion length is 11.37 ± 5.27 mm. Of 89 patients in the ICUS group analyzed to date 68% fulfilled ICUS-criteria of optimal stent expansion (off-line analysis). Procedure time is significantly longer in the in the ICUS group (89 ± 36 vs 61 ± 33 min), fluoroscopy time was similar in both groups (15 ± 13 vs 17 ± 9 min), as well as consumption of balloons (1.7 ± 1.6 vs 1.9 ± 1.0) and stents (1.4 ± 0.9 vs 1.4 ± 0.8). Major adverse events are evenly distributed between groups (death 0/1; acute myocardial infarction 2/3; emergency bypass 2/1; rePTCA 2/4; vascular and bleeding complications 3/2; ICUS vs. angio group).

This interim anaysis shows that ICUS guided stent implantation is a safe approach to optimize stent expansion at the expense of longer procedure times. ICUS criteria of optimal stent expansion could be achieved in 68% of lesions.

1215-106 Interaction of the Wallstent With the Coronary Artery During a Longterm Follow-up: Morphological Assessment by Serial Intravascular Ultrasound With a Motorized Pullback System

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Background: The objective of the study was to assess the effect of the chronic radial pressure of the self-expanding Wallstent on the vessel wall. Therefore serial intravascular ultrasound assessment (IVUS) of the stented segments was performed.

Methods: 25 patients were studied with a standardized motorized pullback device (0.5 mm/sec; 2.9 F; 30 Mhz transducer) immediately and 7.2 ± 3 months after Wallstent implantation. The stented segments were analyzed over the entire length. We examined the mid portions of the stent 5 mm distal from the stent entrance over the mid segment up to 5 mm proximal of the stent outlet. Lumen, stent and vessel planimetry were performed at 1 mm steps. Plaque area (PA) was calculated as vessel area minus lumen area. Neointimal area (NA) was calculated as stent area minus lumen area.

Results: In the mid segments of the stents, the Lumen area (LA) decreased significantly by 8.3% ± 21.2% (12.1 ± 3.4 mm^2 vs. 10.9 ± 3.7 mm^2, $p < 0.0001$). StA increased by 20% ± 15.4% (12.1 mm^2 ± 3.4 mm^2 vs. 15.3 mm^2 ± 3.9 mm^2). NA was 4.4 mm^2 ± 2.2 mm^2, representing 38.6% ± 18.8% of the acute lumen within the stent or 29.2% ± 12.3% of the chronic StA, respectively.

Conclusions: A significant expansion of the stent area can be observed during long-term follow-up. As a result lumen decrease due to neointimal formation is partially balanced by the self-expanding properties of the Wallstent. The chronic barotrauma of the self-expanding stent was not found to cause exaggerated neointimal formation.

1216 Local Drug Delivery

Wednesday, April 1, 1998, 3:00 p.m.–5:00 p.m.
Georgia World Congress Center, West Exhibit Hall Level
Presentation Hour: 3:00 p.m.–4:00 p.m.

1216-77 Efficiency Study of the Annular Balloon Catheter a New Local Drug Delivery Device

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The annular balloon catheter (Nycomed Medical System, Paris, France) is a new rapid exchange system for local drug delivery to the vessel wall, while maintening distal blood flow. The inflatable part of the device is made of a single preformed helically tube having variable pitch and variable diameter. Over the spires a membrane is fixed which defines an anular leaktight infusion chamber with the vessel wall. When inflated, the system deploys a large internal conduit allowing blood flow through the distal coronary artery. The drug can be delivered via an independent injection port to the annular cavity.

Methods: We tested this device in pigs coronary arteries in order to assess 1) the efficiency of drug delivery within the arterial wall using fluorescent tracer (Dextran-rhodamine) 2) the leacktighness of the system by monitoring the pressure into the perfusion chamber 3) the distal blood flow disturbance in the artery using a 0.014 Doppler Flowire 4) the potential histological damages induce by the system.

Result: 1) The fluorescent tracer was circularly distributed in the whole thickness of the wall in every vessel (n = 5) after injection of 1.5 to 3 ml Dextran-rhodamine. 2) The pressure in the infusion chamber remained over the systemic values during all the infusion time except when sides branches were present 3) The coronary blood flow was preserved during the inflation time (15 to 20 minutes) and no arterial occlusion occurred. The percentage of flow variations was 15 ± 5% (n = 7). 3) the set-up of the device into the artery involved a partial abrasion of the endothelium and a localized medial edema was found after the injection.

Conclusion: The annular balloon catheter is suitable for local drug delivery with minimal leakage. The respect of blood flow allows prolonged inflation and injection with excellent tolerance.

1216-85 Local Delivery of ^{125}I-labeled ReoPro to Baboon Brachial Arteries Using an Iontophoretic Balloon Catheter

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Localized delivery of potent antithrombotics after angioplasty might prevent thrombotic events and decrease restenosis while limiting bleeding complications experienced with systemic delivery. We performed bilateral balloon injury in brachial arteries of 12 baboons then gave ^{125}I-labeled ReoPro™ (monoclonal antibody against platelet IIb/IIIa glycoprotein receptor, Centocor B.V.) by one of three routes: intravenous infusion, passive local delivery with a microporous membrane balloon, and active local delivery using an